Safety and Efficacy Study of Electrotransfer of Plasmid AMEP to Treat Advanced or Metastatic Melanoma

This study is currently recruiting participants.
Verified by BioAlliance Pharma SA, November 2009

First Received: January 8, 2010 No Changes Posted

Sponsor:	BioAlliance Pharma SA
Information provided by:	BioAlliance Pharma SA
ClinicalTrials.gov Identifier:	NCT01045915

Purpose

The objective of the present trial is to evaluate the tolerability and the safety of the intratumoural electrotransfer of increasing doses of Plasmid AMEP in patients suffering from advanced or metastatic melanoma and to identify doses that could be effective in man.

Condition	Intervention	Phase
Melanoma	Biological: naked DNA coding for protein AMEP	Phase I

Study Type: Interventional
Study Design: Control: Dose Comparison
Endpoint Classification: Safety Study
Intervention Model: Single Group Assignment
Masking: Open Label
Primary Purpose: Treatment

Official Title: Safety and Efficacy of Intratumoural Electrotransfer of Plasmid AMEP in Patients Suffering From Advanced or Metastatic Melanoma: an Open Phase 1 Trial

Resource links provided by NLM:

MedlinePlus related topics: Melanoma

U.S. FDA Resources

Further study details as provided by BioAlliance Pharma SA:

Primary Outcome Measures:

- Determination of Dose Limiting Toxicity defined as any grade 4 clinical, biological or any life-threatening ECG event occurring during the 9 weeks following treatment
  [Time Frame: 9 weeks] [Designated as safety issue: No]

Estimated Enrollment: 18
Study Start Date: December 2009
Estimated Study Completion Date: September 2011
Estimated Primary Completion Date: June 2011 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Plasmid AMEP electrotransfer: Experimental	Biological: naked DNA coding for protein AMEP 2 injections 1 week interval of 4 increasing doses of plasmid with electrotransfer

Detailed Description:

In this open, multicentre, dose escalation study, successive cohorts of 3 patients suffering from advanced or metastatic melanoma will be electrotransferred increasing doses of Plasmid AMEP into cutaneous melanoma lesions in 2 divided doses at one week interval.

Eligibility

Ages Eligible for Study: 18 Years to 75 Years
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

1. Male or non-pregnant, non-breast feeding female;
2. Aged between 18 and 75 years;
3. Stage IIIB, stage IIIC or stage IV melanoma with:
   - At least 2 cutaneous or subcutaneous non necrotic accessible tumours;
   - Tumour size of 1 to 1.5 cm diameter;
   - No minimum distance between the 2 selected lesions;
4. Progressive melanoma not responding to previous treatments or patients refusing other therapies;
5. Eastern Cooperative Oncology Group (ECOG) performance status ≤ 2;
6. For women of child-bearing age: effective contraception method (oral contraception or intra-uterine device) used for more than 2 months before the 1st administration and to be maintained for 3 months after the last administration of Plasmid AMEP;
7. Having given a written informed consent.

Exclusion Criteria:

1. Significant cardiac arrhythmias, electronic pacemakers, defibrillators, or any implanted electronic device;
2. Recent (less than 6 months) acute vascular diseases (stroke, MI...);
3. History or treatment of seizures within the last 5 years;
4. Clinically significant abnormality at pre-study full physical examination;
5. Any clinically significant ECG abnormalities;
6. Prior systemic therapy or any other antineoplastic treatments within the last 4 weeks, radiotherapy or surgery unrelated to the fields in question are allowed;
7. Abnormal renal function (creatinine plasma level > ULN);
8. Abnormal liver function tests (any of the following):
   - PT < 70%, ASAT, ALAT, alkaline phosphatases, GGT and/or total bilirubin > ULN in the absence of liver metastasis;
   - PT < 70%, ASAT, ALAT > 2 ULN, alkaline phosphatases > 1.5 ULN, GGT > 5 ULN and/or total bilirubin > 3 ULN in the case of liver metastases;
9. Abnormal bone marrow function: haemoglobin < 10g/dL, WBC < 3.109 /L and/or platelet count < 100.103 /L;
10. Clinically significant abnormality in pre-study laboratory tests;
11. Evidence of significant active infection (e.g., pneumonia, wound abscess, etc);
12. Intractable coagulopathy;
13. Any significant disease, including psychiatric and dermatology diseases that may affect the proper evaluation of efficacy or safety;
14. Patients who had participated in another clinical trial in the last 30 days prior to enrolment in the present clinical trial;
15. Patients unwilling or unable to comply with protocol requirements and scheduled visits.

Note: patients with brain metastases, or waiting for other therapies (i.e. isolated limb perfusion) may be included.

Contacts and Locations

Please refer to this study by its ClinicalTrials.gov identifier: NCT01045915

Contacts

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Locations

Denmark

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France

Gustave Roussy Institute — **Not yet recruiting**
Kremlin Bicetre, France, 94805
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Slovenia

Institute of Oncology Ljubljana — **Not yet recruiting**
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Sponsors and Collaborators

BioAlliance Pharma SA

Investigators

Study Director: ATTALI Pierre, MD BioAlliance Pharma

More Information

No publications provided

Responsible Party:	BioAlliance Pharma (Pierre ATTALI, Chief Medical officer)
ClinicalTrials.gov Identifier:	NCT01045915 History of Changes
Other Study ID Numbers:	BA2009/15/01, 2009-013042-88
Study First Received:	January 8, 2010
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Health Authority:	France: Afssaps - French Health Products Safety Agency; Denmark: Danish Medicines Agency; Slovenia: Agency for Medicinal Products - Ministry of Health

Keywords provided by BioAlliance Pharma SA:
Stage IIIB, stage IIIC or stage IV melanoma
Progressive melanoma not responding to previous treatments

Additional relevant MeSH terms:

Neuroectodermal Tumors	Neoplasms, Nerve Tissue
Neoplasms	Nevi and Melanomas
Neoplasms by Histologic Type	Neuroendocrine Tumors
Neoplasms, Germ Cell and Embryonal	Melanoma

ClinicalTrials.gov processed this record on June 09, 2010